

DEC 12 2005

## VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

### A. Submitted by:

Laetitia Cousin  
Director of Regulatory Affairs and Quality Assurance  
NuVasive, Incorporated  
4545 Towne Centre Court  
San Diego, California 92121  
Telephone: (858) 909-1868  
Fax: (858) 909-2068

### B. Device Name

Trade or Proprietary Name:	<i>NuVasive CoRoent ExtenSure System</i>
Common or Usual Name:	Vertebral Body Replacement Device
Classification Name:	Spinal intervertebral body fixation orthosis
Device Class:	Class II
Classification:	§888.3060
Product Code:	MQP

### C. Predicate Devices

The subject *CoRoent ExtenSure System* is substantially equivalent to the *CoRoent System* currently manufactured and distributed commercially in the U.S. by NuVasive (K043205).

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**D. Device Description**

The *NuVasive CoRoent ExtenSure System* is an implantable PEEK vertebral body replacement device indicated for use in the thoracic and lumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of a collapsed, damaged, or unstable vertebral body(s) due to tumor or trauma and to achieve decompression of the spinal cord and neural tissues.

The device is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

**E. Intended Use**

The *NuVasive CoRoent ExtenSure System* is a partial vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of a collapsed, damaged, or unstable vertebral body(s) due to tumor or trauma and to achieve decompression of the spinal cord and neural tissues. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

**F. Comparison to Predicate Devices**

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation.

**G. Summary of Non-Clinical Tests**

Mechanical testing was presented.

**H. Summary of Clinical Tests**

(Not Applicable).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 12 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Laetitia Cousin  
Director of Regulatory Affairs and Quality Assurance  
NuVasive, Inc.  
4545 Towne Centre Court  
San Diego, California 92121

Re: K052210

Trade/Device Name: NuVasive CoRoent™ ExtenSure™ System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: October 20, 2005  
Received: November 15, 2005

Dear Ms. Cousin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
for Mark N. Melkerson

Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K052210

Device Name: CoRoent™ ExtenSure™ System

Indications For Use:

The NuVasive CoRoent ExtenSure System is a partial vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of a collapsed, damaged, or unstable vertebral body(s) due to tumor or trauma and to achieve decompression of the spinal cord and neural tissues. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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